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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FOREMAN, JONATHAN M	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/684,905	VOEGELE ET AL.	
	Examiner	Art Unit	
	JONATHAN ML FOREMAN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,7 and 14-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7 and 14-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/23/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/32/09 has been entered.

Information Disclosure Statement

2. The information disclosure statement filed 6/23/09 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Claim Objections

3. Claim 7 is objected to because of the following informalities: line 15 includes a space between "tip" and the semicolon. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 6 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,712,773 to Viola.

In regard to claim 6, Viola discloses a biopsy instrument including a base assembly (300) including a firing mechanism (Col. 10, lines 36 – 38); a probe assembly (10) detachably mounted to the base (Col. 10, lines 52 – 56), the probe assembly including a cutter assembly including a cutter (58) rotatable about its longitudinal axis; and a piercer assembly including a piercer (22) having a tissue piercing tip (30) and a side tissue receiving port (Col. 5, lines 11 – 12) spaced proximally from the tip, the piercer adapted to be carried distally toward a target by operation of the firing mechanism; and a transmission disposed proximally of the pierce, wherein the transmission is operable to provide motion to the cutter (Col. 6, lines 29 – 33), wherein the transmission receives rotary motion about an axis angled with respect to the cutter's longitudinal axis in that the transmission includes internal gear (70) that receives rotation from gear teeth (96') of drive gear (96) at an angle of 90 degrees with respect to the cutter's longitudinal axis. Furthermore, the Examiner considers the transmission to receive rotary motion about an axis angled with respect to the cutter's longitudinal axis in that the transmission receives rotation from the flexible shaft (226) that can be positioned at an angle with respect to the cutter's longitudinal axis (Figure 1).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6, 712,773 to Viola in view of U.S. Patent No. 6,120,462 to Hibner et al.

In regard to claim 7, Viola discloses a medical device including a biopsy instrument and a source of rotary motion (200; Col. 8, lines 12 – 35) separate from the biopsy instrument; the biopsy instrument comprising a base (300), a probe assembly (10) , and a transmission (70); the base including a firing mechanism (Col. 10, lines 36 – 38); the probe assembly detachably mounted to the base (Col. 10, lines 52 – 56), the probe assembly including a cutter assembly including a cutter (58) having a longitudinal axis; a gear mechanism (68) adapted to move the cutter (Col. 6, lines 31 – 33); a piercer assembly including a piercer (22), a closed distal tip (30), and a tissue receiving port (Col. 5, lines 11 – 12) spaced proximally of the closed distal tip; a probe mount adapted to slideably connect the piercer to the cutter assembly; and the transmission operative to receive rotary motion about an axis angled with respect to the cutter's longitudinal axis in that the transmission includes internal gear (70) that receives rotation from gear teeth (96') of drive gear (96) at an angle of 90 degrees with respect to the cutter's longitudinal axis and transmit rotary motion to the cutter assembly gear mechanism (Col. 6, lines 28 – 33). Furthermore, the Examiner considers the transmission to receive rotary motion about an axis angled with respect to the cutter's longitudinal axis in that the transmission receives rotation from the flexible shaft (226) that can be positioned at an angle with respect to the cutter's longitudinal axis (Figure 1). Viola discloses the piercer having a lumen but fails to disclose the piercer being adapted to receive the cutter. Hibner et al. disclose a medical device including a biopsy instrument including a piercer (70) having a piercing tip (72) and a tissue receiving port (78), the piercer including a lumen and being adapted to receive a rotating cutter (96). The claim would have been obvious because a particular known technique was recognizes as part of the ordinary capabilities of one skilled in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the technique of positioning the rotating

cutter within the piercer as taught by Hibner et al. to the biopsy device as disclosed by Viola for the predictable result of severing tissue that is received within the tissue receiving port.

8. Claims 14, 15 and 17 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,712,773 to Viola in view of U.S. Patent No.5,492,130 to Chiou.

In regard to claims 14, 15 and 17 – 20, Viola discloses a medical device including a biopsy instrument and a source of motion (200; Col. 8, lines 12 – 35) separate from the biopsy instrument; the biopsy instrument comprising a housing (14); a piercer (22) extending distally from the housing and the piercer having a closed distal end (30) and a tissue receiving port (Col. 5, lines 11 – 12) spaced proximally of the closed distal end, the piercer supported with respect to the housing for firing the piercer into tissue (Col. 10, lines 36 – 41); a cutter (58) rotatable and translatable with respect to the tissue receiving port of the piercer (Col. 10, lines 46 – 48), the cutter having a longitudinal axis; and a transmission (70); wherein the biopsy instrument receives at least one input from the separate source of motion along an axis angled with respect to the longitudinal axis of the cutter in that the transmission includes internal gear (70) that receives rotation from gear teeth (96') of drive gear (96) at an angle of 90 degrees with respect to the cutter's longitudinal axis and transmit rotary motion to the cutter assembly gear mechanism (Col. 6, lines 28 – 33). Furthermore, the Examiner considers the transmission to receive rotary motion about an axis angled with respect to the cutter's longitudinal axis in that the transmission receives rotation from the flexible shaft (226) that can be positioned at an angle with respect to the cutter's longitudinal axis (Figure 1). The transmission converts the input to rotary motion of the cutter (Col. 6, lines 29 – 33). The transmission includes at least one gear (70). The instrument receives an input from the second source of motion through an elongate member (Col. 6, lines 33 – 39). The elongate member is a drive cable (Col. 6, line 35). The instrument receives a first input

for translating the cutter from the separate source of motion (218) through a first elongate member (240), and wherein the biopsy instrument receives a second input for rotating the cutter from the separate source of motion (210) through a second elongate member (226). The separate source of motion is disposed in a control unit (200), and wherein the biopsy instrument receives input from the source of motion through a translation shaft (240) comprising a flexible cable in that all materials have at least some degree of flexibility, and from a rotation shaft comprising a flexible cable (226). Viola discloses a mechanism (300) operatively associated with the piercer for firing the piercer into tissue (Col. 9, lines 30 – 33; Col. 10, lines 36 - 38), but fails to disclose by mechanism including at least one spring. Chiou discloses a biopsy device including a firing mechanism having at least one spring (8). The claim would have been obvious because a particular known technique was recognizes as part of the ordinary capabilities of one skilled in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the technique of including at least one spring with the firing mechanism as taught by Chiou for the predictable results of quickly advancing the piercer to the desired tissue location (Col. 6, lines 14 – 15).

9. Claims 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,712,773 to Viola in view of U.S. Patent No.5,492,130 to Chiou as applied above, and further in view of U.S. Patent No. 5,980,545 to Pacala et al.

In regard to claim 16, Viola in view of Chiou disclose a rotatable and translatable (Col. 10, lines 46 – 48) cutter (58) and a transmission, but fail to disclose the transmission including at least one bevel gear. However, Pacala et al. disclose a medical device including a rotatable and translatable cutter (Abstract) and a transmission, wherein the transmission includes at least one bevel gear (28, 34). The claim would have been obvious because the

substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Viola in vie of Chiou and Pacala et al. teach transmissions for providing translation and rotation to a cutter it would have been obvious to one skilled in the art at the time of the invention to substitute one transmission for the other to achieve the predictable results of allowing the cutter (58) to rotate and translate in order to cut a tissue sample.

Response to Arguments

10. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan ML Foreman/
Examiner, Art Unit 3736